REMARKS

Applicants have received and carefully reviewed the Final Office Action mailed April 6, 2010. Currently, claims 1, 4, 5, 8, 28-30, 32, and 33 have been rejected. With this Amendment, claims 1, 28, 32, and 33 have been amended and newly presented claims 34-40 have been added. No new matter has been added. As such, claims 1, 4-5, 8, 28-30, and 32-40 remain pending. Favorable consideration of the following remarks is respectfully requested.

Interview Summary

Applicants thank the Examiner for the courtesy of the interview conducted on May 17, 2010 between Examiner Elizabeth Houston and Applicants' representatives Paul Feng and Ben Nyquist. Claims 1 and 28 were discussed in relation to the Adams reference. In particular, proposed claim language of adding "an intermediate region of at least 10 cm in length disposed between the proximal end region and the distal end region" was proposed to provide further clarification to the claims. No agreement was reached.

Claim Objections

In paragraph 2 of the Final Office Action, claim 33 was objected to as being dependent upon a canceled claim. Claim 33 has been amended to correctly depend from claim 28. Withdrawal of the objection is respectfully requested.

Claim Rejections – 35 U.S.C. § 112

In paragraph 3 of the Office Action, claim 32 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the phrase "the bond" was rejected as lacking sufficient antecedent basis. With this Amendment, claim 32 has been amended to recite "the bond material", which is believed to have sufficient antecedent basis. Withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

In paragraph 5 of the Final Office Action, claims 1, 4, 5, 8, 28-30, 32, and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (U.S. Patent No.

6,273,879) in view of Adams et al. (U.S. Patent No. 6,099,497). After careful review, Applicants respectfully traverse this rejection.

Claim 1 recites:

> 1. A catheter system for positioning a stent at a vessel bifurcation, the catheter system comprising:
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> a catheter including a proximal end and a distal end, the catheter comprising:
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> a first tubular member including a proximal end and a distal end, the first tubular member defining an inflation lumen of the catheter and extending distally from the proximal end of the catheter;
>
> a second tubular member defining a main guidewire lumen, wherein the distal end of the second tubular member is a distal end of the catheter and the proximal end of the second tubular member defines a main guidewire exit port, wherein the main guidewire lumen is configured to receive a main vessel guidewire therethrough, wherein the second tubular member is at least partially disposed within the inflation lumen of the first tubular member;
>
> a balloon including a proximal waist coupled to the first tubular member adjacent to the distal end of the first tubular member and a distal waist coupled to the second tubular member adjacent to the distal end of the second tubular member;
>
> a branch guidewire enclosure positioned alongside the first tubular member, wherein the branch guidewire enclosure defines a lumen configured to receive a branch vessel guidewire therethrough, the branch guidewire enclosure including a proximal end region having a proximal end, a distal end region, and an intermediate region of at least 10 cm in length disposed between the proximal end region and the distal end region, the proximal end of the branch guidewire enclosure defining a branch guidewire exit port; and
>
> a stent having a lumen and a side opening in a wall thereof, the stent positioned about at least a portion of the balloon, and wherein a distal portion of the branch guidewire enclosure is positioned through the lumen of the stent and exits at the side opening;
>
> wherein the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at the proximal end region of the branch guidewire enclosure, wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter.

Without conceding the correctness of the rejection, Applicants have amended claim 1 to recite "a branch guidewire enclosure positioned alongside the first tubular member, wherein the branch guidewire enclosure defines a lumen configured to receive a branch vessel guidewire

therethrough, the branch guidewire enclosure including a proximal end region having a proximal end, a distal end region, and an intermediate region of at least 10 cm in length disposed between the proximal end region and the distal end region, the proximal end of the branch guidewire enclosure defining a branch guidewire exit port" and "wherein the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at the proximal end region of the branch guidewire enclosure, wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter". Nothing in the cited portions of Keith et al. or Adams et al. appears to disclose such features.

Applicants respectfully submit that "an intermediate region of at least 10 cm in length disposed between the proximal end region and the distal end region" in combination with "wherein the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at the proximal end region of the branch guidewire enclosure" cannot be considered as a matter of obvious design choice.

For example, MPEP § 2144.04. IV. A. states:

> ***A. Changes in Size/Proportion***
> *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package "of appreciable size and weight requiring handling by a lift truck" where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) ("mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled." 531 F.2d at 1053, 189 USPQ at 148.).
> In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

In addition, MPEP § 2144.04. VI. C. states:

> ***C. Rearrangement of Parts***
> *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (Claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526

> F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). However, "The mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device." *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

As can be seen, a feature cannot be considered a matter of obvious design choice when the claimed device performs differently than the prior art device and unless the prior art provides a motivation or reason to make the necessary changes in the reference device. Applicants respectfully submit that, as detailed in the specification, the catheter system of claim 1 would appear to perform differently than the prior arts device. For example, page 8, line 32 through page 9, line 4 of the specification recites:

> By distancing the balloon and stent from bond portion 24 (by around 10 cm or more), more flexibility in rotation of the system is provided, facilitating rotational alignment of side opening 34 of stent 32 with the ostium of the branch vessel. Furthermore, stiffness in the area of the stent is reduced by not having extra bond material present in the general region of the stent.

For at least these reasons, "a branch guidewire enclosure positioned alongside the first tubular member, wherein the branch guidewire enclosure defines a lumen configured to receive a branch vessel guidewire therethrough, the branch guidewire enclosure including a proximal end region having a proximal end, a distal end region, and an intermediate region of at least 10 cm in length disposed between the proximal end region and the distal end region, the proximal end of the branch guidewire enclosure defining a branch guidewire exit port" and "wherein the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at the proximal end region of the branch guidewire enclosure, wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter", as recited in claim 1 cannot be considered as a matter of obvious design choice. For at least these reasons, claim 1 is believed to be patentable over Keith et al. in view of Adams et al. For similar reasons and others, claims 4, 5, and 8, which depend from claim 1 and include additional distinguishing features, are believed to be patentable over Keith et al. in view of Adams et al.

Turning now to amended claim 28, which recites:

> 28. A catheter comprising:
> a first catheter tube including a proximal end and a distal end;
> a first distal tube having a proximal end region defining a proximal open end, the first distal tube being configured to receive a first guidewire;
> a second distal tube having a proximal end region defining a proximal open end, the second distal tube being configured to receive a second guidewire;
> a balloon including a proximal waist and a distal waist, the proximal waist being coupled to the first catheter tube adjacent the distal end of the first catheter tube, and the distal waist being coupled to the first distal tube adjacent to a distal end of the first distal tube;
> a stent positioned about at least a portion of the balloon, wherein the second distal tube is configured to exit through a side opening in the stent; and
> a bond material configured to form a bond between the proximal end region of the second distal tube and an intermediate region of the first catheter tube, wherein the proximal open end of the second distal tube remains open to define a second guidewire exit port, wherein the second distal tube is bonded to the first catheter tube only at the bond, and wherein the bond is spaced from the balloon by around 10 cm or more.

For reasons similar to those advanced above in relation to claim 1, as well as other reasons, Applicants respectfully submit that the cited portions of Keith et al. and Adams et al. do not appear to teach or suggest many elements of claim 28, including for example "wherein the second distal tube is bonded to the first catheter tube only at the bond, and wherein the bond is spaced from the balloon by around 10 cm or more." For at least these reasons, claim 28 is believed to be patentable over Keith et al. in view of Adams et al. For similar reasons and others, claims 28-30, 32, and 33, which depend from claim 1 and include additional distinguishing features, are believed to be patentable over Keith et al. in view of Adams et al.

Newly Presented Claims

With this Amendment, newly presented claims 34-40 have been added. For similar reasons discussed above, as well as other reasons, claims 34-40, which depend from claim 1 or claim 28 and include additional distinguishing features, are believed to be patentable over the cited references.

Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

Date: June 30, 2010

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